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Use of a binocular optical coherence tomography system to evaluate strabismus in primary position

Reena Chopra, BSc,¹ Pádraig J. Mulholland, PhD,^{1, 2} Vijay K Tailor, MSc,^{1, 3} Roger
S. Anderson, DSc,^{1, 2} Pearse A. Keane, MD FRCOphth¹

¹NIHR Biomedical Research Centre for Ophthalmology, Moorfields Eye Hospital NHS Foundation
Trust and UCL Institute of Ophthalmology, London, United Kingdom

²Optometry and Vision Science Research Group, School of Biomedical Sciences, Ulster University,
Coleraine, United Kingdom

³Experimental Psychology, UCL, London, United Kingdom

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Correspondence and reprint requests:

Pearse A. Keane, MD FRCOphth, NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS
Foundation Trust and UCL Institute of Ophthalmology, London, United Kingdom. Tel: +44 207 523
3411 Fax: +44 207 566 2334 Email: p.keane@ucl.ac.uk

26 **Running Head:**

27 Automated, quantitative assessment of strabismus using binocular OCT

28 **Keywords:**

29 Binocular

30 Optical coherence tomography

31 Automated

32 Diagnostics

33 Strabismus

34 **Abbreviations:**

35 APCT - Alternating Prism Cover Test

36 OCT – Optical Coherence Tomography

37 LoA – Limits of Agreement

38

39 **Figures:**

40 2

41

42 **Tables:**

43 1

44 Key Points

45

46 **Question:** Can a new form of optical coherence tomography (OCT) known as
47 'binocular OCT' be used to measure the size of strabismus?

48 **Findings:** This study included 15 participants with strabismus and 15 healthy
49 individuals. Binocular OCT imaging correctly revealed the type and direction of the deviation
50 in all participants, including both horizontal and vertical deviations. The size of strabismus
51 measured with binocular OCT had fair agreement with the alternating prism cover test.

52 **Meaning:** Binocular anterior segment OCT imaging can provide clinicians with a
53 precise measurement of strabismus, which may be useful for diagnosis and monitoring.

Abstract

Importance: Current clinical methods for assessing strabismus can be prone to error. Binocular OCT has the potential to assess and quantify strabismus objectively and in an automated manner.

Objective: To evaluate the use of a binocular optical coherence tomography (OCT) prototype to assess the presence and size of strabismus.

Design, Setting, and Participants: Fifteen participants with strabismus recruited from Moorfields Eye Hospital NHS Foundation Trust, London, UK, and fifteen healthy volunteers underwent automated anterior segment imaging using the binocular OCT prototype. All participants had an orthoptic assessment including alternating prism cover test (APCT) prior to imaging. Simultaneously acquired pairs of OCT images, captured with one eye fixating, were analysed using ImageJ to assess the presence and angle of strabismus.

Main Outcomes and Measures: The direction and size of strabismus measured using binocular OCT was compared to that found using APCT.

Results: The median age for participants with strabismus was 55 years (interquartile range 33-66.5 years), and 50 years (interquartile range 41-59 years) for healthy group. The median magnitude of horizontal deviation was 20 Δ (interquartile range 13-35 Δ), and 3 Δ for vertical deviation (interquartile range 0-5 Δ). Binocular OCT imaging correctly revealed the type and direction of the deviation in all 15 strabismus participants, including both horizontal and vertical deviations. APCT and OCT measurements were strongly correlated for both horizontal (Pearson's $r = 0.85$, 95% confidence interval (CI) 0.60-0.95; $P < 0.001$) and vertical ($r = 0.89$, CI 0.69-0.96; $P < 0.001$) deviations. In the healthy cohort, 9 participants had a latent horizontal deviation on APCT (median magnitude 2 Δ , range 2-4 Δ). Six were orthophoric. Horizontal deviations were observed on OCT imaging in 12 of the 15 participants, and a vertical deviation was visible in 1 participant.

80 **Conclusions and Relevance:** These findings suggest that binocular anterior
81 segment OCT imaging can provide clinicians with a precise measurement of strabismus.
82 The prototype can potentially incorporate several binocular vision tests that will provide
83 quantitative data for the assessment, diagnosis, and monitoring of ocular misalignments.

Introduction

Strabismus is a common condition that can affect both children and adults.^{1, 2} Clinical assessments designed to measure ocular misalignment often require specialist orthoptic expertise and good patient cooperation. An alternating prism cover test (APCT) is most commonly used, however, the endpoint of such testing can be subtle or variable, and is prone to inter- and intra-observer error, particularly in less cooperative children.^{3, 4} Electronic instruments that use infrared light to track eye position of both eyes simultaneously such as video goggles⁵ and gaze trackers⁶ have been developed to increase the precision of measurement but are mainly used for research purposes.

Optical coherence tomography (OCT) devices are becoming ubiquitous to eye clinics as they provide objective and quantitative data about ocular structures to aid the diagnosis and monitoring of eye disease. In this report we demonstrate an application of a prototype binocular optical coherence tomography system (Envision Diagnostics, El Segundo, CA) that acquires anterior segment images of both eyes simultaneously, even with one eye fixating, and in an automated manner. By analyzing simultaneously acquired pairs of anterior segment images, the presence of strabismus can be identified. We evaluate the use of anterior segment OCT as a method of assessing strabismus and measuring the angle of deviation.

Methods

Participants with strabismus were prospectively recruited from clinics at Moorfields Eye Hospital NHS Foundation Trust, London, UK, as part of the EASE study (ClinicalTrials.gov Identifier: NCT02822612). Healthy volunteers were recruited from staff members at the hospital. Written informed consent was obtained from all participants in the study. All participants were required to have no significant hearing impairment that would affect their ability to respond to instructions delivered by the device. A conversational level of English was required for users to understand the instructions, and to be able to communicate with the device via an English language voice recognition system. No participants were excluded based on disease status to ensure our cohort consisted of everyday users of eye care services. All underwent orthoptic assessment prior to binocular OCT examination, including visual acuity measurement and APCT at distance in primary position, with habitual refractive error correction if appropriate. Approval for data collection and analysis was obtained from a UK National Health Service Research Ethics Committee (London-Central). The study adhered to the tenets of the Declaration of Helsinki.

Binocular OCT examination

All participants underwent binocular OCT examination as described elsewhere.⁷ Briefly, this is an automated prototype device that acquires OCT images of the anterior and posterior segments of both eyes simultaneously using a tunable swept-source laser without requiring an operator. The device uses a Maxwellian view system to simulate distance fixation. The fixation target was presented to the non-deviating eye in the strabismus group, selected manually prior to examination. Therefore, the primary deviation was measured on OCT. For healthy participants, the target was presented to the dominant eye (right eye in all

participants). The spherical equivalent of the user's habitual refractive error is corrected within the device.

Measurement of angle

A volume comprising 128 B-scans of the anterior segment was acquired by the device in the horizontal and vertical planes. Only a single central anterior segment image was used for each plane for analyses. The central image can be deduced by the visualization of the corneal vertex reflection in the fixing eye.⁸ This hyperreflective line was used as a surrogate for the visual axis. The image captured at the same time point was used for the fellow non-fixing eye. The images were adjusted to 16.5x14.9 aspect ratio as they are acquired at 16.5mm width and 14.9mm depth. ImageJ, a widely use open-source Java image analysis program was used to measure the difference in angle in degrees between the fixing and non-fixing eye. A line was drawn between the pupil margins at the posterior epithelium of the iris for both eyes. These landmarks were chosen as they were visible in both horizontal and vertical scans. The angle between the lines was calculated as the angle of deviation (Figure 1).

Outcome measures

1. The direction of the deviation was determined by the direction of the fellow eye with respect to the fixating eye in both horizontal and vertical scans. This was compared to the direction of the misalignment found using APCT for distance fixation.
2. The size of the misalignment was compared to that found using distance APCT. Values in prism diopters (Δ) were converted to degrees using the following formula:⁹

$$\text{degrees} = \tan^{-1}(\Delta/100) \times 180/\pi$$

Results

Twelve participants had concomitant strabismus, one of which had glaucoma and strabismus. One participant had a decompensated strabismus as a consequence of loss of vision after a retinal detachment. Two participants had an acquired restrictive incomitant strabismus related to sphenoid wing meningioma, and thyroid eye disease. These are described further in Table 1. The median age was 55 years (interquartile range 33-66.5 years). Thirteen subjects were Caucasian, and two subjects were Asian. Seven of the 15 subjects were female. The median magnitude of horizontal deviation was 20Δ (interquartile range $13\text{--}35\Delta$), and 3Δ for vertical deviation (interquartile range $0\text{--}5\Delta$). Mean spherical equivalent was $+0.53\text{D} \pm 2.19$ (range sphere -2.50 to $+5.50\text{DS}$, range cylinder 0 to -3.50DC). The cohort of healthy participants had no manifest deviation. Nine healthy participants had a latent deviation for distance, and 6 were orthophoric. The median age of this group was 50 years (interquartile range $41\text{--}59$ years). Twelve healthy participants were Caucasian, two were Asian, and one subject was Black. Eight of the healthy participants were female. Mean spherical equivalent for this cohort was $-0.51\text{D} \pm 1.45$ (range sphere -3.50 to $+2.75\text{DS}$, range cylinder 0 to -2.50DC). All participants understood the examination and were cooperative, as discussed further in a usability study of the device.⁷

Direction and size of misalignment

Orthoptic assessment revealed five participants in the strabismus group had a horizontal deviation only, one participant had a vertical deviation only, and nine participants had both horizontal and vertical deviations. A torsional element was not detected in any participants. Binocular OCT imaging correctly identified the direction of misalignment in all 15 strabismus participants, including both horizontal and vertical deviations. Three out of the five

participants assessed as having a horizontal deviation only using APCT were also found to have an additional vertical deviation on binocular OCT imaging (Table 1).

There was a strong correlation between the measurement of strabismus using APCT and the measurement calculated from the OCT images for both horizontal (Pearson's $r=0.85$, 95% confidence interval (CI) 0.60-0.95; $P<0.001$) and vertical ($r=0.89$, CI 0.69-0.96; $P<0.001$) deviations. The confidence intervals indicate a strong relationship between the two methods. Bland-Altman¹⁰ plots show heteroscedasticity where the agreement between the methods decreases as the size of the deviation increases. There was a mean difference of -0.30° ($\sim -0.52\Delta$) for horizontal misalignment and -2.20° ($\sim -3.84\Delta$) for vertical misalignment. The 95% limits of agreement (LoA) for horizontal misalignment were between 9.55° ($\sim 16.82\Delta$) and -10.16° ($\sim -17.55\Delta$). For vertical misalignment the limits of agreement were narrower between 2.66° ($\sim 4.65\Delta$) and -7.06° ($\sim -12.38\Delta$). Regression on the Bland-Altman plots show no significant proportional bias for horizontal misalignments ($P=0.957$), however show a significant relationship for vertical misalignments ($P=0.007$).

In the healthy cohort, 8 had an exophoria (median magnitude 2Δ , range $2-4\Delta$ ($1.15-2.29^\circ$)), one participant had an esophoria measuring 2Δ , and 6 participants were orthophoric, measured using distance APCT. One participant had a vertical deviation on near APCT. No other participants in this group had a vertical or torsional component at distance or near. In the 8 exophoric participants, 6 had a misalignment corresponding to an exo-deviation on OCT (median magnitude 5.25° ($\sim 9.19\Delta$), interquartile range, $2.63-6.49^\circ$ ($\sim 4.59-11.38\Delta$), one had an eso-deviation on OCT measuring 8.61° ($\sim 15\Delta$), and one participant had no deviation on OCT. From the 6 orthophoric participants, 3 had an exo-deviation on OCT (range $2.93-6.38^\circ$) and 1 had an eso-deviation (4.09°). The single participant with an esophoria did not have any measured deviation on the binocular OCT. Two participants measured as orthophoric on APCT was also orthophoric on binocular OCT. A vertical component corresponding to a left hyper-deviation was identified in 1 healthy participant on OCT measuring 2.26° ($\sim 3.95\Delta$). This participant did not have a vertical latent deviation on distance APCT, but did have a left hyperphoria measuring 5Δ on near APCT. A weak

205 correlation was observed between APCT and OCT measurements for horizontal deviation in
206 this group (Pearson's $r=0.06$, $P=0.830$, CI 0.14-0.85).

207

Discussion

In this paper we explore OCT-derived quantification and assessment of strabismus angle using a novel prototype binocular OCT system.

The device was able to correctly identify the direction of the deviation in the strabismus group, including both horizontal and vertical elements. The device also indicated a vertical deviation ($<4\Delta$) in three participants who were recorded as vertically orthophoric. Small deviations ($<2\Delta$), particularly vertical deviations, may not be reliably perceived by the unaided eye on cover testing^{11, 12} but may be visible on the OCT. The binocular OCT identified a horizontal deviation in 12 participants of the healthy cohort. In 9 of these participants, the direction of the deviation on OCT was the same as the latent deviation found on APCT. This suggests that the binocular OCT is measuring both manifest and latent components.

In horizontal misalignment, the agreement between the methods tended to decrease as the size of the deviation increased. A similar heteroscedastic pattern was found for vertical misalignments however our sample was skewed towards smaller deviations. The LoA were larger than the inter-examiner variability found by de Jongh et al.¹³ for horizontal deviations (10Δ). This would suggest that our method is not in strong agreement with APCT. However, a larger sample is required to confirm inferences from Bland-Altman plots. Differences between the methods may be partly attributable to the limited scale of prism diopters - as the deviation becomes larger, the difference in degrees between each prism diopter also increases. In addition, increments between diopters in prism bars increase as the power increases. For example, between $1-10\Delta$, prism power increases in increments of 1 diopter, whereas between $20-50\Delta$, power increases by 5Δ increments, forcing the orthoptist to choose the closest prism that neutralises the misalignment. Whereas, the binocular OCT is able to measure strabismus angle more precisely using a scale of degrees instead of diopters. A longitudinal and repeatability study is required to validate this method

and to investigate whether OCT-derived measurements are valuable for monitoring the change in size of misalignment over time.

There are several limitations of the device at present, however it is likely that these can be overcome in future iterations. A significant limitation of the device includes the inability to ascertain whether a heterophoria or heterotropia is present. We observed deviations in both the healthy and strabismus cohorts. It is likely that the device is reliably identifying manifest vertical and horizontal components in the strabismus group. However, if the device was used as a screening device for manifest strabismus, it may have a high false positive rate particularly for horizontal deviations as observed in the healthy cohort. The unique features of the binocular OCT could potentially be extended to perform a cover test by switching the fixation between the eyes to differentiate between these entities. In the present study, all strabismus participants had a constant deviation. Those with intermittent deviations may not be identified using the current prototype setup. Real-time video OCT with 3D-rendering would also aid measurement of torsional deviations. By bringing the fixation target closer to the eyes, the device has the capacity to simulate near fixation to measure deviation at various distances. In addition, the current prototype setup performs ocular motility testing by displaying the fixation target at different locations of the screen.⁷ Strabismus with varying gaze or motion, in addition to alternating fixation, may help discern between primary and secondary deviations in incomitant strabismus.

The prototype currently corrects a mean spherical equivalent of the user's habitual correction to aid visualization of the fixation target. Refractive error can affect the size of the deviation, and the inability to correct cylindrical error may contribute to the differences observed between the methods. Additionally, although the device simulates distance fixation, proximal convergence may attribute to differences between APCT and OCT measurements. In one exophoric participant, a significant eso-deviation was found on OCT. Monocular viewing conditions has been shown to cause accommodative convergence which may affect these results.¹⁴ In subsequent devices with binocular viewing conditions this may be reduced. Some users of the device may naturally fixate closer than distance fixation, and

263 this could explain the larger exo-deviations found on OCT compared to APCT in the healthy
264 cohort. This may also explain the vertical component found in the one healthy participant
265 who had a vertical deviation at near.

266 Our method of using the pupil margin as a reference plane for tilt may contribute to
267 error. An anatomical landmark such as Schwalbe's line may be less variable as this cannot
268 change dynamically like the iris, but may be less discernible, particularly in vertical scans
269 due to occlusion of this landmark by the eyelids. Visual axis data could potentially provide
270 more accurate measurements of strabismus. This could be determined by using retinal OCT
271 images of the fovea that are also acquired using the device. The device currently does not
272 measure axial length which prevents mapping the retinal and anterior segment images to
273 each other to determine the visual axis. However, if axial length data could be obtained, the
274 visual axis could potentially provide a reliable method of measuring strabismus using OCT,
275 particularly in strabismus with normal retinal correspondence.

276 In summary, we present a novel application of OCT imaging to detect and measure
277 ocular misalignment. The advantage of this method is the ability to detect subtle differences
278 in the size of strabismus that may not be visible to the naked eye. This is encompassed
279 within a device that can perform several functional tests in addition to whole-eye imaging.
280 The automated manner of the device means a highly skilled specialist is not required to take
281 measurements of the deviation, therefore making it ideal for screening purposes. As
282 discussed, measuring strabismus using prism bars has limitations particularly at larger
283 angles. The binocular OCT can provide a more precise measurement of this angle using
284 degrees (with out without converting back to prism diopters). This may be useful for
285 measuring strabismus over time, before and after surgery, or for patients undergoing
286 botulinum toxin injections. Although the current setup has many caveats, future iterations of
287 the binocular OCT may allow quicker and more accurate assessments of strabismus
288 particularly where orthoptists are limited with huge patient volumes. In addition, the device
289 can output objective quantitative data for ocular misalignments as well as for other
290 diagnostic tests,⁷ aiding the diagnosis and monitoring of eye disease.

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Author Contributions:

R.C., P.J.M., R.S.A., P.A.K. were involved in the study setup

R.C., V.K.T. collected the data for the study

R.C. analysed the data

R.C., P.J.M., V.K.T., R.S.A., P.A.K. wrote the manuscript

Access to data:

318 R.C. had full access to all the data in the study and takes responsibility for the integrity of the
319 data and the accuracy of the data analysis.

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350 conditions with an open-view sensor. *Biomed Opt Express*. 2015;6(10):4200

Table

Table 1. Orthoptic assessment and binocular optical coherence tomography measurements for fifteen participants with strabismus. Vertical deviation measurements obtained using OCT are indicated as hyper- or hypo- with respect to the strabismic eye (i.e. the eye with a horizontal deviation if present).

Participant	Clinical diagnosis	Binocular status in primary position	Age	Visual acuity (logMAR)		Mean spherical equivalent (both eyes) (DS)	Distance prism cover test (6 metres)	Prism cover test - equivalent angle in degrees		Angle measured on OCT (degrees)		OCT angle converted to prism (rounded to nearest diopter)
				Right	Left			Horizontal	Vertical	Horizontal	Vertical	
1	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppression	35	0.60	0.00	0 (unaided)	12 Δ BI 5 Δ BD R/L	6.84	2.86	6.14 (exo)	11.13 (RE hyper)	11 Δ BI 20 Δ BD R/L
2	LE/Alternating esotropia (Duane's syndrome)	No diplopia, LE suppression	24	-0.10	-0.10	-0.63	45 Δ BO	24.23		18.67 (eso)	2.23 (LE hyper)	34 Δ BO 4 Δ BD L/R
3	RE fully accommodative esotropia	No diplopia, binocular	23	0.62	0.02	+2.88	6 Δ BO 4 Δ BD R/L	3.43	2.29	6.17 (eso)	4.87 (RE hyper)	11 Δ BO 9 Δ BD R/L

		single vision										
4	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppression	63	0.00	0.16	+5.38	45 Δ BI 3 Δ BD R/L	24.23	1.72	29.34 (exo)	2.93 (RE hyper)	56 Δ BI 5 Δ R/L
5	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppression	50	0.18	-0.02	-0.06	25 Δ BI	14.04		19.83 (exo)	2.28 (RE hypo)	36 Δ BI 4 Δ BD L/R
6	LE childhood esotropia	No diplopia, LE suppression	47	0.16	0.76	-2.44	25 Δ BO	14.04		11.08 (eso)	0.00	20 Δ BO
7	LE longstanding distance esotropia	Diplopia	74	0.00	0.00	-1.25	14 Δ BO 4 Δ BD L/R	7.97	2.29	12.96 (eso)	2.18 (LE hyper)	23 Δ BO 4 Δ BD L/R
8	LE myopic esotropia	Diplopia	74	-0.10	0.00	-0.5	25 Δ BO 2 Δ BD R/L	14.04	1.15	23.74 (eso)	3.48 (LE hypo)	44 Δ BO 6 Δ BD R/L
9	LE hypertropia (secondary to thyroid eye disease)	Diplopia	62	-0.10	0.00	+1.25	20 Δ BD L/R		11.31	0.00 (ortho)	18.15 (LE hyper)	33 Δ BD L/R

10	RE residual esotropia with hypertropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppression	31	-0.08	-0.12	+3.13	14 Δ BO 5 Δ BD R/L	7.97	2.86	2.07 (eso)	5.89 (RE hyper)	4 Δ BO 10 Δ BD R/L
11	RE exotropia with hypertropia (decompensated after loss of vision from a right retinal detachment)	Diplopia	31	0.78	-0.20	0 (unaided)	45 Δ BI 3 Δ BD R/L	24.23	2.29	16.97 (exo)	2.02 (RE hyper)	31 Δ BI 4 Δ BD R/L
12	LE exotropia with hypotropia (secondary to left sphenoid wing meningioma)	Diplopia	74	-0.04	0.30	+1.25	20 Δ BI 25 Δ BD R/L	11.31	14.04	14.75 (exo)	14.26 (LE hypo)	26 Δ BI 25 Δ BD R/L
13	LE residual exotropia (prior strabismus surgery for childhood exotropia)	No diplopia, LE suppression	55	0.00	0.48	0 (unaided)	60 Δ BI 6 Δ BD R/L	30.96	3.43	26.33 (exo)	6.30 (LE hypo)	49 Δ BI 11 Δ BD R/L
14	RE age-related distance esotropia	Diplopia	68	0.16	0.00	-1.50	6 Δ BO	3.43		1.33 (eso)	0.00	2 Δ BO
15	LE myopic esotropia (and glaucoma)	Diplopia	61	-0.10	0.10	-0.25	16 Δ BO	9.09		10.99 (eso)	1.54 (LE hyper)	19 Δ BO 3 Δ BD L/R

Figures and Figure Legends

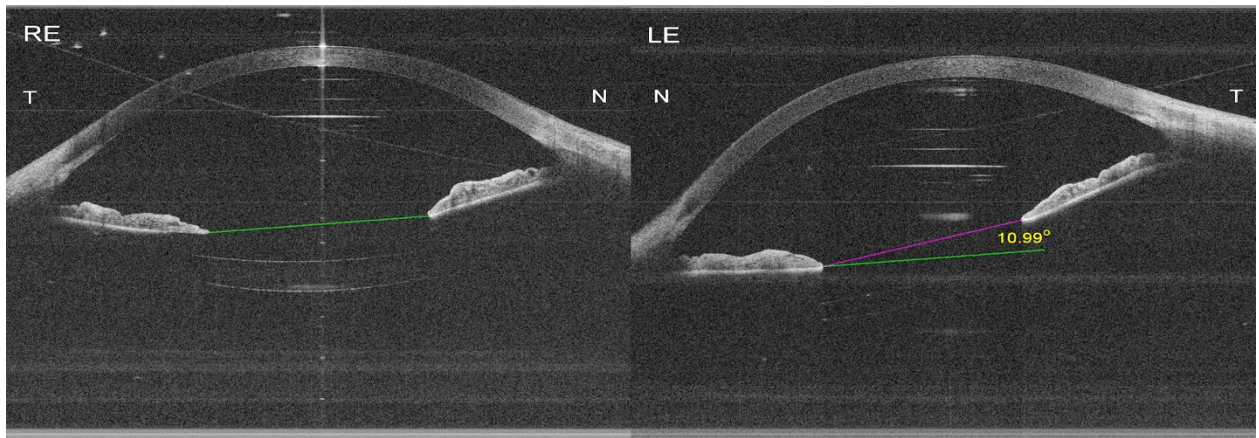


Figure 1.

Title: Simultaneously acquired pair of anterior segment optical coherence tomography (OCT) images obtained for Participant 15.

Caption: The right eye is the fixating eye, and the left eye is the strabismic eye. The angle of the deviation is calculated by measuring the tilt of the eye with respect to the fixating eye. The pupil margins are used as landmarks to measure tilt. This pair of images indicate a left esotropia. (N = nasal, T = temporal)

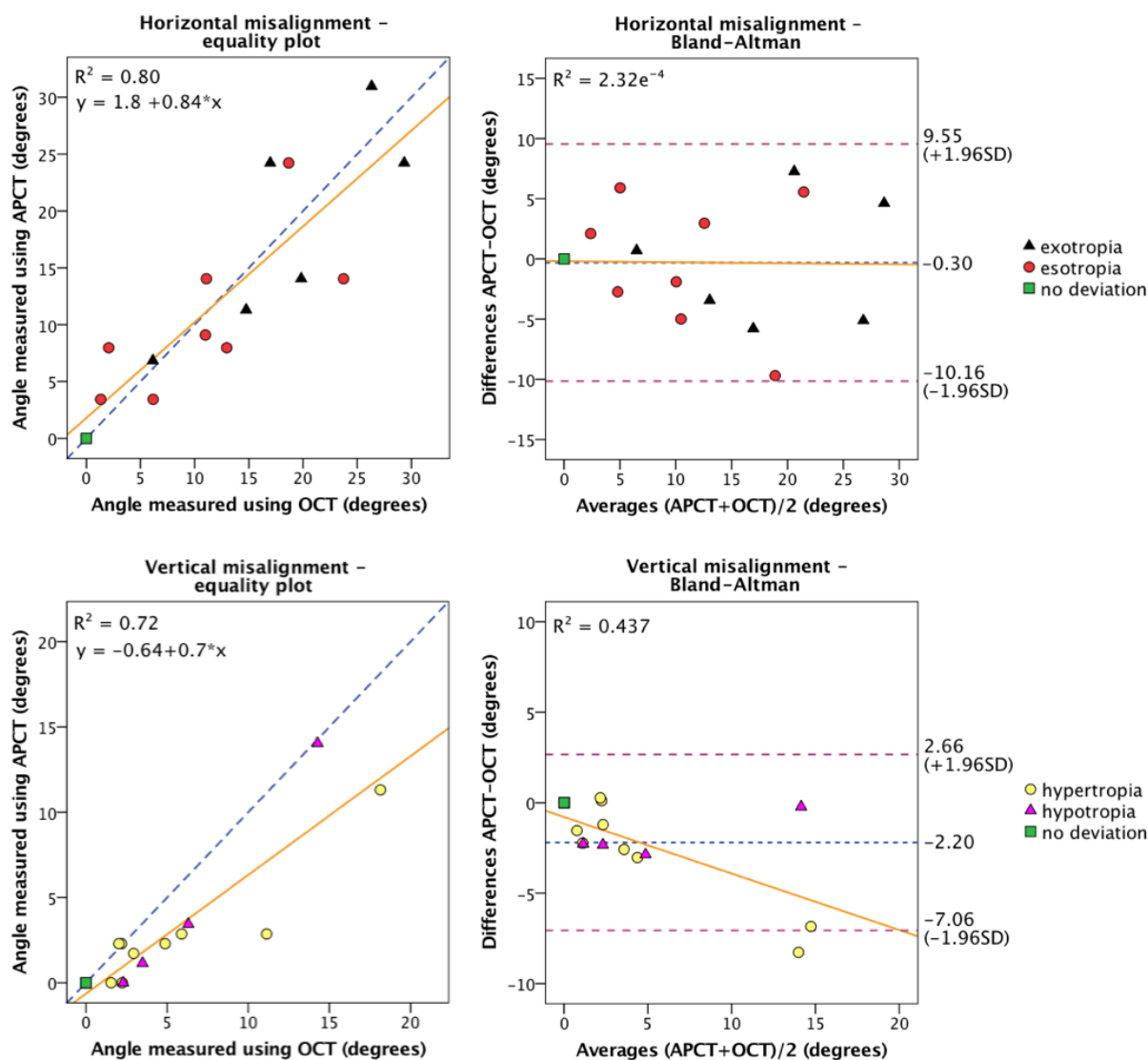


Figure 2.

Title: Equality and Bland-Altman plots comparing agreement of measurements obtained using APCT and binocular OCT.

Caption: Measurements for horizontal misalignments vertical misalignment are presented in the top and bottom plots respectively. For vertical deviations, pink triangle markers represent a hypo- deviation with respect to the strabismic eye. Green indicates no measured deviation with either method. Regression lines are represented in orange. For the equality plots the dashed line represents perfect agreement. The reference lines on the Bland-Altman plots show the mean and 95% limits of agreement (LoA). The LoA were $\pm 9.85^\circ$ from the mean for horizontal misalignments, and $\pm 4.86^\circ$ for vertical misalignments.